# Public consultation on the draft *Guidelines on compounding of medicines*

28 April 2014

## Responses to consultation questions

**Please provide your feedback as a Word document (or equivalent)[1] to pharmacyconsultation@ahpra.gov.au by close of business on Monday 30 June 2014.**

### Stakeholder Details

*If you wish to include background information about your organisation please provide this as a separate word document (not PDF).*

| **Organisation name** |
|---|
| Therapeutic Goods Administration (TGA) |
| **Contact information**<br>*(please include contact person's name and email address)* |
| Dr Larry Kelly<br>[redacted] |

### Your responses to consultation questions on the draft *Guidelines on compounding of medicines*

| 1. Do the draft guidelines clearly differentiate between simple compounding and complex compounding? |
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| Yes. |
| 2. Do the draft guidelines clearly outline which requirements apply to pharmacists who undertake either or both types of compounding (simple and/or complex compounding), and which requirements apply only to pharmacists who undertake complex compounding? |
| No comment. |
| 3. Is the content of the draft guidelines helpful? |
| The draft guidelines provide additional guidance and clarification compared to the current edition. |

[1] You are welcome to supply a PDF file of your feedback in addition to the word (or equivalent) file, however we request that you do supply a text or word file. As part of an effort to meet international website accessibility guidelines, AHPRA and National Boards are striving to publish documents in accessible formats (such as word), in addition to PDFs. More information about this is available at www.ahpra.gov.au/About-AHPRA/Accessibility.aspx.

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| 4. Is there any content that needs to be changed, added or deleted in the draft guidelines? |
| Changes are suggested below, shown by underlining.<br><br>Page 7: 'Despite the exemptions listed above, compounded medicines are not exempted from meeting the quality standards or advertising requirements set out in the Therapeutic Goods Act 1989 (Cwlth)'.<br><br>Page 15, Section 14 Advertising<br><br>The following changes are suggested for clarity, to focus on advertising to the public, and to include the pre-approval process.<br><br>paragraph 1: Advertising of products and/or services to the public by compounding pharmacists must be done in accordance with the Therapeutic Goods Act 1989 (Cwlth), the AgVet Code, and/or the Board's Guidelines for advertising of regulated health services.<br><br>paragraph 2: Compounded medicines are subject to the advertising provision of the Therapeutic Goods Act 1989 (Cwlth), the Therapeutic Goods Regulations 1990 and the Therapeutic Goods Advertising Code. Compounded medicines that are Schedule 3 (but not listed in Appendix H of the Poisons Standard), Schedule 4 and Schedule 8 cannot be advertised to the public.<br><br>Paragraph 3: In the case of advertising the availability of a specific formulae or product, for a medicine that can be advertised (generally, medicines that are unscheduled, Schedule 2 or Schedule 3 and included in Appendix H of the Poisons Standard), pharmacists are expected to provide evidence of its efficacy in the advertisement (refer to *3.3 Substantiation of claims* in the Board's *Guidelines for advertising of regulated health services).* Advertisements for compounded medicines that can be advertised also require pre-approval by the Secretary of the Department of Health if they are to be placed in certain types of media, including (but not limited to) billboards, newspaper, magazines, and television (for further information about which types of media require pre-approval, see www.tga.gov.au). |
| 5. Do you have any suggestions for questions to be answered in Frequently Asked Questions developed by the Board to support the guidelines? |
| No comment. |
| 6. Is the purpose of the practice profile clearly explained in the draft guidelines? |
| No comment. |
| 7. Do you have any other comments on the draft guidelines? |
| No comment. |

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